EXHIBIT B

Guidance for Industry and FDA

Exhibit C

Employment Contract

Nonjudicial employees that received paid leave and/or Compensatory Time ("CT") for attending vaccination appointments are still required to upload proof of fully vaccinated status through the share point site in order to be exempt from weekly testing. Under no circumstances will employees who received paid leave and/or CT for attending vaccination appointments be granted paid leave for purposes of weekly testing.

2. Start of Testing Program

The weekly testing program starts on September 7, 2021. On September 7, 2021 every Kronos supervisor, Administrative Judge and Supervising Judge ("supervisor") will receive an email with a link to the UCS Employee Web Portal ("Portal") which will contain a list of all of the judges or employees ("participants") under their supervision who must submit weekly proof of COVID tests. (Again, judges and nonjudicial employees who have submitted an approved proof of vaccination will be excluded from this list).

While participants will not be required to submit proof of testing during the week of September 7, 2021, they should use this time to coordinate a time with their supervisor to be tested during their regular work hours in the workweek that follows, i.e. the week starting September 13, 2021. Nonjudicial employees will be provided with one (1) hour of paid leave without charge to accruals each week for purposes of undergoing this testing.

Participants must upload proof of testing within one workday from the day they were tested. Supervisors will need to check the Portal each workday to ensure each participant has timely submitted proof of testing.

3. Supervisor Scheduling

Supervisors will be responsible for ensuring that all participants on their September 7, 2021 "Portal" list have coordinated/scheduled a date and time to undergo testing during the week that follows.

To the extent practicable, and subject to the operational needs of the court and the availability of testing appointments, the supervisor and participant may want to coordinate/schedule a set day and time each week for the participant to undergo testing, i.e., establish a recurring testing hour each week. Supervisors should be flexible, where possible, to accommodate a participant's scheduled or unscheduled leave or available testing appointments.

Nonjudicial employees are entitled to one (1) hour of excused leave per week which will be granted upon substantiating that testing was conducted on the date the employee was released from work for their test. Supervisors will make every effort to coordinate/ schedule release time at a mutually convenient time, taking into consideration that some

A-2

From: c.mone@aol.com,
To: lmarks@nycourts.gov,
Subject: Honorable Lawrence Marks
Date: Wed, Sep 8, 2021 6:00 am

Honorable Lawrence Marks, September 8, 2021

The following statement addresses the office of court administration's new mandatory covid testing policy slated to begin September 7, 2021. Judge Difiore has repeatedly claimed that the office of court administration is following CDC guidelines. According to CDC data, vaccinated individuals can contract and transmit covid just as readily as unvaccinated do. As a matter of fact, vaccinated employees are testing positive in the courts everyday. If this policy has been put in place to ensure the safety of all employees, and also in accordance with the CDC's current guidelines, it would call for the testing of all employees indiscriminately. The policy states that the office of court administration will only test employees who are either unvaccinated or unwilling to disclose their medical status. If the office of court administration moves forward with mandatory testing only of employees not enrolled in their orange card program it is extremely biased and discriminatory. Forcing healthy employees, absent any symptoms to be tested is implicitly unjust. The one hour time constraint that the office of court administration mandated for testing adds an additional layer of undue stress, not only on employees, but also on court operations. According to the office of court administration's mandatory testing policy if a healthy employee refuses to test weekly the office of court administration intends to forcefully send that employee home unfit to serve, label that employee absent without authorization, and possibly withhold pay. This is punitive and retaliatory. Will the court of administration be requiring attorney's or members of the public to provide proof of a weekly covid test? On February 5, 2021 Judge Difiore was quoted as saying "any case involving claims of discriminatory conduct would necessitate a full disciplinary hearing ". Plain and simple, this is discrimination and requires an Anti-Discrimination panel. We feel the office of court administration are required to have our concerns of discrimination against us heard through a formal hearing.

The following addresses the court of administration's unconstitutional vaccine mandate slated to begin September 27, 2021. First and foremost the office of court administration's refusal to negotiate with its employees union representation is prejudicial. We pay union dues and are unable to be fairly represented. Mandating a vaccine under the threat of termination lacks empathy. Taking away an employee's bodily autonomy under the guise of public safety is morally offensive. The vaers reporting system has over 50,000 adverse effects from receiving the vaccine. Will the office of court administration be held liable for injuries or death? Where is the office of court administration's consideration of natural immunity? It is already September 8, and we have no instructions on how to apply for medical or religious exemptions. How are employees expected to have time to schedule appointments with their doctors or spiritual advisors if that is the route they so desire? Sending home employees as unfit to serve, who are in good standing and regularly report to work as scheduled is absurd. Have you considered the stress you are putting on your employees disregarding their free will with the threat of termination? Both of these mandates are discriminatory. Since the chief judge refuses to negotiate with our union leadership we are appealing to you Judge Marks, we urge you to reverse course on this unlawful policy.
We appreciate the office of court administration's immediate attention to this matter

Thank you
Christopher Mone
Court Officer Richmond Family

This statement is supported by many court employees including the following:
Colleen Mone, Michael Mallen, Kerri Beyers, Robert Lavanco, Matt Joseph, Joe Colasuonno, Peter Scalfani, Andrew Park, Michael Decicco, Michael Williams, Gina Ervolino, Andrea Stefanski, Alex Rivera, Jason

Gambino, Michael LaRosa, Daniel Corazza, Stephen Toscanini, Nicole Toscanini, Mary Alexis, Dominick Lepore, Kyrie Teel, Nicole Fioreto, Karla Mariragas, Nicole Nicoletti, Chris Pizutto, John Sanginari

Sent from my Verizon, Samsung Galaxy smartphone

A-3

NEW YORK STATE
Unified Court System
OFFICE OF COURT ADMINISTRATION

LAWRENCE K. MARKS
CHIEF ADMINISTRATIVE JUDGE

NANCY J. BARRY, ESQ.
CHIEF OF OPERATIONS

JUSTIN A. BARRY, ESQ.
CHIEF OF ADMINISTRATION

MEMORANDUM

September 10, 2021

To: All Non-Judicial Personnel

From: Nancy J. Barry
Justin Barry

Re: Mandatory Vaccination Requirement

As previously announced, the Unified Court System will require all judges and non-judicial personnel to be vaccinated by September 27, 2021, unless otherwise approved for an exemption due to medical reasons or sincerely held religious beliefs, as explained more fully below.

This memorandum will outline the program as it relates to non-judicial personnel. The Chief Administrative Judge will outline the program for judges in a separate document.

Proof of Vaccination

All non-judicial personnel must be fully vaccinated against COVID-19 by September 27, 2021, or as soon thereafter as medically practicable provided they have received at least one dose of a COVID-19 vaccine by such date.[1]

To this end, no later than September 27, 2021, all non-judicial personnel must either submit proof that they: (1) are fully vaccinated; or (2) have received at least one dose of any COVID-19 vaccine. This proof must be submitted through the UCS SharePoint site https://nycourts.sharepoint.com/sites/COVID-19/CPV as outlined in Section (1) of our September 1, 2021 Memorandum (Mandatory Testing Program – Supplemental Information).

[1] Fully vaccinated is defined as: two weeks after receiving a second dose of a two-dose vaccine, such as the Pfizer or Moderna vaccines; or two weeks after receiving a single-dose vaccine, such as the Johnson and Johnson vaccine.

Acceptable proof of having received at least one dose of a COVID-19 vaccine is a copy of the front **and** back of the employee's vaccination card. For fully vaccinated employees, a screenshot of the employee's Excelsior Pass is also acceptable. Those employees, who submit proof of having received their first dose of a two-dose vaccine, will be required to submit proof of having received the second dose within the medically recommended timeframe, i.e., typically 3 weeks from the first dose, using the same UCS SharePoint site referenced above.

Employees, who have submitted proof of vaccination by September 27, 2021 but are not yet fully vaccinated because they must receive a second dose and/or they must wait an additional two weeks after their last dose, will be subject to the Mandatory Testing Program until such time as they are fully vaccinated.

Exemptions

Exemptions to the mandatory vaccination requirement will be considered for employees with underlying medical conditions that make receiving the COVID-19 vaccine unsafe for them and employees with sincerely held religious beliefs and practices that prohibit them from receiving a COVID-19 vaccine.

Employees seeking a medical or religious exemption to vaccination must submit their request by 5:00 p.m. on September 27, 2021 using the appropriate exemption form (see attached Exhibit A – Medical Exemption Request Form and Exhibit B – Religious Exemption Request Form). The completed Exemption Request Form must be scanned and uploaded through the UCS Employee Web Portal located at https://portal.nycourts.gov/ExemptionCOVID19Vaccination/. Instructions for uploading these Forms will be available on the Portal, which will "go live" on September 20, 2021.

No exemption requests will be considered unless they are fully completed on the appropriate form and filed through the Portal.

Applications for medical exemptions must be accompanied by documentation from the employee's medical health professional. Applications for religious exemption must contain the employee's written, signed and notarized statement detailing the religious basis for his/her objection to COVID-19 vaccination and the religious principle(s) that guide the objections to COVID-19 vaccination. Employees submitting an exemption application will be notified, in writing, of the decision [which, if granted, will include the expiration date of the exemption] or, that more information is needed in order to consider the employee's request for an exemption, as soon as practicable after their request is filed.

Employees who timely file a request for exemption will be subject to the Mandatory Testing Program while their request is being reviewed. Those employees who are granted a medical or religious exemption to vaccination will be subject to the Mandatory Testing Program during the specified exemption period.

An employee who receives written notice that their request for medical or religious exemption was denied will have ten workdays from the date of the notification to submit proof of having received

at least one dose of a COVID-19 vaccine and must otherwise comply with the provisions set forth in "Proof of Vaccination" above.

Non-Compliance

Employees who fail to comply with the provisions of this Policy are prohibited from reporting to work and may be considered absent without authorization for which approval to charge accruals may be denied, until they have taken steps to remedy their non-compliance. Continued failure to comply may result in disciplinary action, up to and including termination.

Additional Information

Non-judicial personnel are reminded that they are eligible for Excused Leave and/or Compensatory Time for becoming vaccinated (up to 3.5 hours per appointment upon submission of the requisite proof of same).

Non-judicial personnel must continue to follow all other safety and operational protocols.

We are deeply grateful to our staff for their collaboration in the ever-evolving guidance surrounding COVID-19 and their commitment to keeping themselves, their colleagues and all who conduct business in our facilities safe.

cc: Hon. Lawrence Marks
Hon. George Silver
Hon. Edwina Mendelson
Hon. Norman St. George
Administrative Judges
NYC Chief Clerks
District Executives
OCA Directors
Chief Michael Magliano

A-4a

Chris Mone
c.mone@aol.com

Janet Difiore, Chief Judge
Jdifiore@nycourts.gov
212-661-6787

Nancy J. Barry, Chief of Operations
nbarry@nycourts.gov
646-386-4600

Justin A. Barry, Chief of Administration
jbarry@nycourts.gov
646-386-4600

Lawrence K. Marks, Chief Administrative Judge
Lmarks@nycourts.gov
212-428-2884

CONFIDENTIAL COMMUNICATION
29 CFR §1630.14(c)(1)

September 10th 2021.

RE employment discrimination and retaliation based on disability

Greetings,

Each of you must be aware by now that your (New York State Unified Court System) Covid-19 policies to impose medical interventions such as mask-wearing, testing and experimental drugs including the vaccinations are patently illegal. You are the people that know better and of which a higher degree of understanding and conduct is incumbent upon you, yet you are participating in these discriminatory policies in spite of your expertise and professional obligations.

Be advised that in spite of your ignoring my first complaints over this matter, I am continuing to document your violations of the law and discrimination based upon disability by opening a confidential file with human resources. I intend to make this a matter of public record by filing a complaint against the court for its violations of Title I of the Americans with Disabilities Act.

I'm not required to take experimental drugs as a condition of my employment and I've never waived my rights to medical privacy or informed consent. No matter what your professional standing and whether or not there is any pandemic, no laws have changed and I have never waived any of my medical privacy rights. Judges and attorneys of all people should know this, as I'm sure you are aware that it is a crime to falsify government and court records as you are now doing in contumacious disregard for the law.

You are not permitted to regard me as having a disability, then make a record of such disability and then compel me to submit to your medical interventions without my consent. Please be advised of the law, Title I of the Americans with Disabilities Act, 29 CFR Part 1630.9(d). No laws have changed, you already know this. You have no greater duty of care, in fact, you are violating your duty of care.

You each need to remediate yourselves of the actual laws of the State of New York as compiled and published in the New York State Public Health Manual, A Guide for Judges, Attorneys and Public Health Professionals and the Americans with Disabilities Act.

Sincerely,

Chris Mone

A-40

PLACE STICKER AT TOP OF ENVELOPE TO THE RIGHT OF THE RETURN ADDRESS FOLD AT DOTTED LINE

SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3.
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- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

C. DIFIORE, L. MARKS, N. BARRY
J. BARRY
25 Beaver St
New York NY 10004

9590 9402 6934 1104 5518 16

2. Article Number *(Transfer from service label)*

7020 3160 0001 2670 7536

PS Form 3811, July 2020 PSN 7530-02-000-9053

COMPLETE THIS SECTION ON DELIVERY

A. Signature
X [signature] ☐ Agent ☐ Addressee

B. Received by *(Printed Name)* COURD-14

C. Date of Delivery 9.15.21

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

3. Service Type

- ☐ Adult Signature
- ☐ Adult Signature Restricted Delivery
- ☑ Certified Mail®
- ☐ Certified Mail Restricted Delivery
- ☐ Collect on Delivery
- ☐ Collect on Delivery Restricted Delivery
- ☐ Insured Mail
- ☐ Restricted Delivery
- ☐ Priority Mail Express®
- ☐ Registered Mail™
- ☐ Registered Mail Restricted Delivery
- ☐ Signature Confirmation™
- ☐ Signature Confirmation Restricted Delivery

Domestic Return Receipt

A-59

Chris Mone
c.mone@aol.com

Carolyn Grimaldi, Human Resources
New York State Unified Court System
212-428-2884
Cgrima11@nycourts.gov

CONFIDENTIAL COMMUNICATION
29 CFR §1630.14(c)(1)

September 10th 2021.

RE employment discrimination based on disability

Hello Ms. Grimaldi,

My first complaint of this nature was ignored, but I have documented the correspondence and I'm advising you to respond this time. This is a confidential communication that I am requesting be included into my personnel file and I want this and subsequent communications to be kept confidential within human resources. I'm documenting acts of discrimination based upon disability, intimidation, retaliation and harassment by Janet Difiore, Nancy J. Barry, Justin A. Barry and Lawrence K. Marks, of which I have been subjected to on-the-job. I also want to speak confidentially to the court's designated employee or representative for matters involving grievances under Title I of the Americans with Disabilities Act as it pertains to on-the-job discrimination and retaliation based upon disability.

The court and these employees regards me as having a disability (contagious disease) **without any diagnosis or individualized assessment** and has also made a record of such disability by **mis-classifying me** as having, a mental or physical impairment that substantially limits one or more major life activities.1

Please explain why the court and its employees are discriminating against me based upon a disability that the court and its employees are regarding me as having, and the reason why the court has made and continues to make a record of such disability? I am invoking my rights under Title I of the Americans with Disabilities Act as a qualified individual with a disability.

I am being regarded as having a contagious disease without any individualized assessment and continually being asked for my medical records and to submit to medical examinations and interventions (accommodation measures) without any informed consent. It has been extremely difficult to perform my employment duties because of these interruptions and harassment.

Regarding the accommodation measures described in the court's memorandum and administrative order dated September 1st 2021, its website at https://www.nycourts.gov/ and related communications, please be advised that I am not required to accept these or any accommodations under Title I of the ADA, 29 CFR Part 1630.9(d). Moreover, I am not required to prove any "exemption" but you alone have the burden of proving that I am a direct threat. I demand to review the records you have relied upon to determine that I am a direct threat. If you have some legal authority that overrides this, please provide me with a legal citation.

Be advised that 29 CFR Part 1630 prohibits state agencies (employers) from requiring medical examinations or making disability-related inquiries of employees unless such examination or inquiry is shown to be job-related and consistent with business necessity under 42 U.S.C. §12112(d)(4); 29 CFR §1630.14(c)

My questions are:

[1]This behavior is also symptomatic of a mental illness known as Factitious Disorder (DSM, 5th Ed.)

1. Why do you regard me as having a disability and what records have you made of this?

2. What physician, what medical records, and what complaint made by a physician to a health officer, and "orders of isolation and quarantine" do you rely upon for diagnosing me as having a contagious disease? Please include all, evidence, court records and records from the individualized assessment used in making this determination or diagnosis as required under Title I of the Americans with Disabilities Act.[2]

3. Please identify the statute and regulation imposing your legal duty of care that requires you to protect me and others from any contagious disease.

4. Please provide a copy of documentary evidence from the departments of health or labor establishing the existence of a disease that has been isolated by modern scientific standards and documentary evidence proving that such disease is airborne, deadly and contagious.

5. Please identify your insurable risk with a copy of your insurance binder showing that you are insured for protecting employees from a contagious disease, and any adverse health consequences they may suffer as a result of your accommodation measures.

6. Regarding the accommodation measures, **a)** why have you refused to include notice that these are made under an emergency use authorization period, and refused to disclose the risks and benefits of the product, and also advise me of my right to either accept or refuse the product,[3] and **b)** which of these accommodation measures has the proven efficacy to prevent transmission or infection of the contagious disease for which you regard me as having?

7. How are your requests for my medical information and submitting to medical examinations and interventions necessary for the performance of my employment duties?

8. Why are you able to diagnose me with a deadly disease and impose restrictions and medical interventions without my informed consent, without any physician's oversight or judicial approval, yet I am required to obtain written permission from my physician to exercise my rights to informed consent and medical privacy? We can stipulate that I have never waived any of my rights to medical privacy which includes the right of informed consent as a condition for employment.

9. Please disclose records of the court's budget approval for using public funds for administering or prescribing health control measures without judicial oversight and approval, without any licensing, insurance or medical training and without the supervision of any physician.

Please identify the designated employee responsible for resolving matters concerning on-the-job discrimination based upon disability.

Be advised that it is illegal to condition my employment upon submitting to your accommodation measures, this constitutes discrimination based upon disability, a violation of 29 CFR Part 1630, for which I would have a claim for employment discrimination based upon disability.

Sincerely,

Chris Mone

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[2] 29 CFR 1630.2 *et seq.* And 45 CFR Part 84.2 *et seq.*
[3] 21 USC 360bbb-3

A-5b

SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3.
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- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:

CAROLYN GRIMALDI
25 BEAVER ST
NEW YORK, NY 10004

9590 9402 6934 1104 5517 93

2. [illegible] 7020 3160 0001 2670 7512

COMPLETE THIS SECTION ON DELIVERY

A. Signature
x G.B. ATTY ☐ Agent ☐ Addressee

B. Received by (Printed Name) COVID-19 | C. Date of Delivery 9.15.21

D. Is delivery address different from item 1? ☐ Yes
If YES, enter delivery address below: ☐ No

3. Service Type

☐ Adult Signature	☐ Priority Mail Express®
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☒ Certified Mail®	☐ Registered Mail Restricted Delivery
☐ Certified Mail Restricted Delivery	☐ Signature Confirmation™
☐ Collect on Delivery	☐ Signature Confirmation Restricted Delivery
☐ Collect on Delivery Restricted Delivery	
[illegible]estricted Delivery (over $500)	

PS Form 3811, July 2020 PSN 7530-02-000-9053 Domestic Return Receipt

A - 6

From: jbarry@nycourts.gov,
To: c.mone@aol.com,
Subject: FW: Honorable Lawrence Marks
Date: Mon, Sep 13, 2021 2:35 pm

Dear Officer Mone:

Your e-mail to Chief Administrative Judge Marks, dated September 8, 2021, was referred to me. As the Chief Judge stated in her most recent Monday address, the Unified Court System's (UCS) mandatory vaccination policy is "the best and most responsible action that we can take at this time, in the face of the rapidly spreading COVID variants, and as part of our effort to protect the health and safety of our court family and ensure the safest possible environment for the many thousands of New Yorkers who visit and conduct business in our courthouses every day."

The scientific evidence is clear that widespread vaccination is the best tool available for protecting judges, employees and other court users in our courthouses. The CDC states on its website that "people fully vaccinated with an mRNA vaccine (Pfizer-BioNTech or Moderna) are less likely than unvaccinated persons to acquire SARS-CoV-2 or to transmit it to others." Available evidence also suggests that COVID-19 vaccines are highly effective against hospitalization and death from COVID-19. Though the risk of breakthrough infections in fully vaccinated people is not eliminated, unvaccinated people are much more likely to get COVID-19 than fully vaccinated individuals. New York City has compiled data that shows unvaccinated New Yorkers are 3.1 times more likely to get COVID-19 than fully vaccinated New Yorkers, and unvaccinated individuals are 10 times more likely to be hospitalized than those who are fully vaccinated.

The CDC does not call for indiscriminate testing. The CDC states, "[i]t is recommended that fully vaccinated people with no COVID-19-like symptoms and no known exposure should be exempted from routine screening testing programs, if feasible." Though UCS recognizes that the current weekly testing requirement for unvaccinated individuals burdens court operations, we have determined that testing of unvaccinated individuals is critical to maintain the safety of our employees and judges.

UCS's mandatory vaccination policy was announced shortly after the Food and Drug Administration granted full approval to the Pfizer-BioNTech COVID-19 vaccine for individuals 16 years of age and older on August 23, 2021. The FDA gives full approval when it has enough data to demonstrate that a vaccine is safe and effective for most people who get them, and it has had the opportunity to fully review and approve the entire vaccine process. It is expected that the FDA will give full approval to additional COVID-19 vaccines shortly. UCS' decision and other governmental entities' determinations to implement the mandatory vaccination is not discrimination because vaccination status is not a protected classification under federal or state law. UCS will grant exemptions for individuals with sincerely held religious beliefs and medical conditions that would make it unsafe for them to receive a vaccine.

We would strongly encourage any employees with concerns about the vaccine, such as the ones you describe, to consult their medical health professional and seek guidance. We will carefully review all exemption requests and, where necessary, open a dialogue with the medical professional and be guided once again by the science and the employee's condition.

Sincerely yours,

Justin Barry

Chief of Administration

NYS Office of Court Administration

25 Beaver Street, Room 1145

New York, NY 10004

(212) 428-5554

jbarry@nycourts.gov

From: c.mone <c.mone@aol.com>
Sent: Wednesday, September 8, 2021 6:01 AM
To: Hon. Lawrence Marks <lmarks@nycourts.gov>
Subject: Honorable Lawrence Marks

Honorable Lawrence Marks, September 8, 2021

The following statement addresses the office of court administration's new mandatory covid testing policy slated to begin September 7, 2021. Judge Difiore has repeatedly claimed that the office of court administration is following CDC guidelines. According to CDC data, vaccinated individuals can contract and transmit covid just as readily as unvaccinated do. As a matter of fact, vaccinated employees are testing positive in the courts everyday. If this policy has been put in place to ensure the safety of all employees, and also in accordance with the CDC's current guidelines, it would call for the testing of all employees indiscriminately. The policy states that the office of court administration will only test employees who are either unvaccinated or unwilling to disclose their medical status. If the office of court administration moves forward with mandatory testing only of employees not enrolled in their orange card program it is extremely biased and discriminatory. Forcing healthy employees, absent any symptoms to be tested is implicitly unjust. The one hour time constraint that the office of court administration mandated for testing adds an additional layer of undue stress, not only on employees, but also on court operations. According to the office of court administration's mandatory testing policy if a healthy employee refuses to test weekly the office of court administration intends to forcefully send that employee home unfit to serve, label that employee absent without authorization, and possibly withhold pay. This is punitive and retaliatory. Will the court of administration be requiring

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We appreciate the office of court administration's immediate attention to this matter

Thank you
Christopher Mone
Court Officer Richmond Family

This statement is supported by many court employees including the following:
Colleen Mone, Michael Mallen, Kerri Beyers, Robert Lavanco, Matt Joseph, Joe Colasuonno, Peter Scalfani, Andrew Park, Michael Decicco, Michael Williams, Gina Ervolino, Andrea Stefanski, Alex Rivera, Jason Gambino, Michael LaRosa, Daniel Corazza, Stephen Toscanini, Nicole Toscanini, Mary Alexis, Dominick Lepore, Kyrie Teel, Nicole Fioreto, Karla Mariragas, Nicole Nicoletti, Chris Pizutto, John Sanginari

Sent from my Verizon, Samsung Galaxy smartphone

A-7

From: cgrima11@nycourts.gov,
To: c.mone@aol.com,
Subject: September 10, 2021 Letter Re: Employment Discrimination Based on Disability
Date: Thu, Sep 16, 2021 4:26 pm
Attachments: (31K)

Good Afternoon,

I'm in receipt of your below email w/attached letter dated September 10, 2021, as well as the duplicate hard copies of same that were transmitted to me via regular mail and certified mail [received today].

Please be advised that your Personnel File is not maintained by the Division of Human Resources -- rather, it is maintained locally in the Administrative Office for your Court.

Nonetheless, an employee's Personnel File may only contain authorized records documenting the employee's work history, conduct and/or work performance such as: resumes or applications; appointment letters; probationary term notifications; statements of receipt of employee handbook, discrimination claim policy, sexual harassment policy, etc.; declination to participate in sick leave bank program; receipts for keys and other custodial items; documents relating to professional development programs, diplomas and certificates; applications for leave; performance evaluations; counseling memoranda; disciplinary records; grievances and resulting step decisions; reports of work-related injuries; requests for reassignment; requests for reclassification, military orders; and resignation and terminations letters.

Specifically prohibited from placement in an employee's Personnel File are: any documents or records pertaining to confidential medical and/or health information [including any back-up medical related to leaves of absence]; **complaints filed pursuant to Discrimination Claim Procedures** or Sexual Harassment Policy; complaints filed pursuant to State or Federal Occupation Safety and Health Acts; letters from creditors or letters of garnishment; background screening; and financial disclosures documents.

Based on the foregoing, the request for your September 10, 2021 letter "RE: employment discrimination based on disability" to be placed in your Personnel Folder must be denied. However, as I am mandated to report complaints of harassment and/or discrimination to the Office of the Inspector General [which is charged with maintaining documents and records pertaining to such claims], I have forwarded your letter to that Office for review and processing as it deems necessary and appropriate.

To the extent your September 10th letter relates to the correspondence you previously sent to Hon. Lawrence K. Marks [dated September 8, 2021] wherein you raised a number of concerns about the Court System's COVID-19 Vaccination and/or Testing Policy(ies), attached for your reference is a copy of my September 14th email to you in response to same which I've forwarded to the Office of the Inspector General along with your September 10th letter.

As indicated in my September 14th email, any questions or concerns you may have regarding the Court System's Vaccination and/or Testing Policy(ies) should be referred to your Union.

Regards,

Carolyn Grimaldi, Esq.

Director of Human Resources

Office of Court Administration

25 Beaver Street, 7th Floor

New York, NY 10004

Tel: (212) 428-2515

From: c.mone <c.mone@aol.com>
Sent: Sunday, September 12, 2021 10:59 PM
To: Carolyn Grimaldi <cgrima11@nycourts.gov>
Subject: I am sharing '1_5039861775000928589' with you

Sent from my Verizon, Samsung Galaxy smartphone

Mr. Mone,

Your reliance on the Chief Judge's statement that all discrimination cases will necessitate a full hearing is misplaced, as this refers to disciplinary hearings for employees [entitled to same under the Rules or applicable collective bargaining agreement] who have been found to have engaged in biased and/or discriminatory conduct. Indeed, there is no internal or administrative mechanism under which employees may demand a

A-8

From: MIGBM@nycourts.gov,
To: c.mone@aol.com,
Subject: RE: I am sharing '1_5039861775000928585' with you
Date: Fri, Sep 17, 2021 2:53 pm

Chris Mone, the Office of the Managing Inspector General for Bias Matters is in receipt of your email.

However, based on the facts presented in your complaint, we do not have jurisdiction to investigate this matter.

Thank you.

From: c.mone <c.mone@aol.com>
Sent: Wednesday, September 15, 2021 4:19 PM
To: MIGBM <MIGBM@nycourts.gov>
Subject: FW: I am sharing '1_5039861775000928585' with you

Ms Moy,

This is a confidential communication sent to Janet Difiore, Lawrence Marks, Justin Barry, and Nancy Barry. To date all named parties have regretfully ignored it.

I am documenting the office of court administration's behavior on this and all other matters.

Thank you

Chris Mone

Sent from my Verizon, Samsung Galaxy smartphone

-------- Original message --------

From: "c.mone" <c.mone@aol.com>

Date: 9/12/21 11:05 PM (GMT-05:00)

A-9

Chris Mone
83 Windsor Road
Staten Island, New York 10314
c.mone@aol.com

David L. Reinman, ADR Coordinator New York District Office EEOC 33 Whitehall Street, 5th Floor New York, NY 10004 david.reinman@eeoc.gov 929-506-5306	CRTIU Supervisor New York District Office EEOC 33 Whitehall Street, 5th Floor New York, NY 10004
Eva Moy, OMIGBM Office of Court Administration 25 Beaver Street New York, New York 10004 Phone: (646) 386-3507 email: migbm@nycourts.gov	New York State EEOC Division of Human Rights complaints@dhr.ny.gov

September 20, 2021

For New York District Office EEOC

Charge of Discrimination
and
Request for Investigation and Mediation

STATEMENT IN SUPPORT OF COMPLAINT

I am making this complaint against my employer for its discrimination against me based upon disability. The name and address of my employer is: New York State Unified Court System, 25 Beaver Street, New York, New York 10004. The EEOC has the authority and legal duty investigate this complaint.

My employer regards me as having a disability: a contagious disease.

My employer has made a record of such disability.

My employer has failed to conduct any individualized assessment to determine if I am a direct threat to anyone. My employer has failed to engage in any interactive process with me concerning disability rights or resolutions.

Witness List:

1. Janet Difiore, Chief Judge, Jdifiore@nycourts.gov
2. Nancy J. Barry, Chief of Operations, nbarry@nycourts.gov
3. Justin A. Barry, Chief of Administration, 646-386-4600, jbarry@nycourts.gov
4. Lawrence K. Marks, Chief Administrative Judge, Lmarks@nycourts.gov
5. Carolyn Grimaldi,Director of Human Resources grima11@nycourts.gov
6. Eva Moy, The Managing Inspector General for Bias Matters migbm@nycourts.gov
7. Dennis Quirk, President New York State Court Officers Association nyscoa@aol.com

I have asked to speak confidentially with my employer's designated employee or representative that is responsible for resolving matters involving the Americans with Disabilities Act and grievances thereunder, but my employer refuses to provide me access to such a person.

Instead, my employer has offered various accommodation measures including but not limited to mask-wearing, staying six feet away from others, frequent hand-washing, collection, use and storage of my vital statistics, histological samples and biometric data and biometric identifiers without adequate or proper notice, adequate disclosures, adequate data retention security or my informed consent, working in isolation, video-graphic and audio-graphic communications in lieu of face to face communications, working behind clear shielding, and injections of certain types of suspensions which are being called "vaccinations" yet do not prevent infection or transmission of any contagious disease and in fact create more disabilities by altering the normal function of my immune system and other cellular functions. My employer has not merely "offered" such accommodation measures, but threatened me with penalties including those described herein for refusing such accommodations in violation of 29 CFR Part 1630.9(d).

I then informed my employer that I do not accept such "accommodations" because I have not requested any accommodation and because I am a qualified individual with a disability that substantially limits my ability to engage in one or more major life activities.

My employer asked me to describe my disability and discuss it with certain employees, even though such disability does not adversely affect my ability to perform the duties of my employment, and has done so without any offer or attempt to make such disclosures in confidence or privately.

I have requested information regarding the risks and benefits of my employers accommodation measures and in response, my employer has retaliated against me by humiliating me in front of others, by reprimanding me and has threatened or intimidated or

coerced me with the threat of suspension of my pay, reduced hours or pay or the termination of my employment for refusing such accommodation measures instead of providing me with the information I requested so that I could make an informed decision.

I have exercised my right to refuse such accommodation measures and proposed instead that I be permitted to perform my employment duties without harassment, retaliation, coercion or intimidation as a result of my exercise of such rights, and my employer has prevented and interfered with this occurring.

I have not requested reasonable modifications but only that I be permitted to perform my employment duties without harassment, retaliation, coercion or intimidation.

My employer has instead retaliated against me for exercising my rights under the Americans with Disabilities Act by threatening me with disciplinary measures and penalties for refusing such accommodation measures, including but not limited to suspension or reduction of pay, limiting my access to the premises where I work, segregation, isolation, termination of employment, exclusion from programs or services that would permit me to improve my employment skills or become eligible for advancement, and denied me the possibility for promotion even when I was eligible or would become eligible.

Each day my employer permits and encourages other employees, including my supervisor and managers to harass and intimidate me and ask me for medical, health and other personal information that does not pertain to, or is not necessary for, the performance of my employment duties.

I am thereby being denied equal access to the same programs, activities, benefits, jobs or other opportunities for which I am otherwise qualified, while other employees are not. I am being segregated, excluded and relegated to lesser services by my employer based solely upon disability.

My employer has written and adopted policies that exacerbate my disabilities and create disabilities while also encouraging others to retaliate against me for exercising my rights under the Americans with Disabilities Act.

My employer has failed or refused to fulfill its duty to aid and encourage me in the exercise of my rights which are protected under the Americans with Disabilities Act.

My employer has demonstrated by the actions of its employees and by its own written policies that it intends to continue such violations and failures to comply with the law and violation my rights.

REQUEST FOR INVESTIGATION AND MEDIATION

By filing this Charge, I am formally requesting an investigation and mediation hearing to resolve these issues. I request that my Charge be entered manually and a hearing be scheduled. I request the CRTIU Supervisor to enter my Charge into the EEOC system personally as I do not find the online portal acceptable or accessible for entering my

Charge. I request a written response from the CRTIU Supervisor confirming that my Charge has been filed within 14 business days of receipt of this Notice.

Chris Mone

Enclosure Copies:

1.) Notice of Employment Discrimination & Harassment Based on Disability

A-10

Chris Mone
c.mone@aol.com

Carolyn Grimaldi, Human Resources New York State Unified Court System 212-428-2884 Cgrima11@nycourts.gov	Eva Moy, Office of the Managing Inspector General for Bias Matters Office of Court Administration Phone: (646) 386-3507 migbm@nycourts.gov

CONFIDENTIAL COMMUNICATION
29 CFR §1630.14(c)(1)

September 20, 2021

RE: Amended Notice of Employment Discrimination Based on Disability

Hello Ms. Grimaldi and Ms. Moy,

This is a confidential communication that I am requesting Carolyn Grimaldi to include in the appropriate personnel file for complaints of discrimination which the EEOC can access and I want this and subsequent communications to be kept confidential within human resources and the OMIGBM. I'm documenting acts of discrimination based upon disability, intimidation, retaliation and harassment by Janet Difiore, Nancy J. Barry, Justin A. Barry and Lawrence K. Marks, of which I have been subjected to on-the-job. I also want to speak confidentially to the court's designated employee or representative for matters involving grievances under Title I of the Americans with Disabilities Act as it pertains to on-the-job discrimination and retaliation based upon disability who I believe is Eva Moy.

I understand that The Office of the MIG for Bias Matters conducts confidential investigations in connection with allegations of discrimination and bias that affect the conditions and terms of employment, or that relate to services provided by court system personnel. I request Eva Moy to open a complaint and investigation on my behalf regarding on-going discrimination, harassment and retaliation I am experiencing by my employer.

I am documenting that the court and these employees are regarding me as having a disability (contagious disease) **without any diagnosis or individualized assessment** and have also made a record of such disability by **mis-classifying me** as having, a mental or physical impairment that substantially limits one or more major life activities.[1]

I wish to open a complaint and have an investigation determine why the court and its employees are discriminating against me based upon a disability that the court and its employees are regarding me as having, and why the court has made and continues to make a record of such disability? I am invoking my rights under Title I of the Americans with Disabilities Act as a qualified individual with a disability.

I am being regarded as having a contagious disease without any individualized assessment and continually being asked for my medical records and to submit to medical examinations and interventions (accommodation measures) without any informed consent. It has

1 This behavior is also symptomatic of a mental illness known as Factitious Disorder (DSM, 5th Ed.)

been extremely difficult to perform my employment duties because of these interruptions and harassment.

Regarding the accommodation measures described in the court's memorandum and administrative order dated September 1st 2021, its website at https://www.nycourts.gov/ and related communications, please advise the employer that I am not required to accept these or any accommodations under Title I of the ADA, 29 CFR Part 1630.9(d). Moreover, I am not required to prove any "exemption" but the employer alone has the burden of proving that I am a direct threat. I demand to review the records the employer has relied upon to determine that I am a direct threat. If there is some legal authority that overrides my rights under the ADA, please provide me with a legal citation.

Be advised that 29 CFR Part 1630 prohibits state agencies (employers) from requiring medical examinations or making disability-related inquiries of employees unless such examination or inquiry is shown to be job-related and consistent with business necessity under 42 U.S.C. §12112(d)(4); 29 CFR §1630.14(c)

I have several questions that I would like answered by my employer and I request Eva Moy to incorporate getting them answered as part of the OMIGBM investigation.

My questions for my employer are:

1. Why do you regard me as having a disability and what records have you made of this?

2. What physician, what medical records, and what complaint made by a physician to a health officer, and "orders of isolation and quarantine" do you rely upon for diagnosing me as having a contagious disease? Please include all, evidence, court records and records from the individualized assessment used in making this determination or diagnosis as required under Title I of the Americans with Disabilities Act.[2]

3. Please identify the statute and regulation imposing your legal duty of care that requires you to protect me and others from any contagious disease.

4. Please provide a copy of documentary evidence from the departments of health or labor establishing the existence of a disease that has been isolated by modern scientific standards and documentary evidence proving that such disease is airborne, deadly and contagious.

5. Please identify your insurable risk with a copy of your insurance binder showing that you are insured for protecting employees from a contagious disease, and any adverse health consequences they may suffer as a result of your accommodation measures.

6. Regarding the accommodation measures, **a)** why have you refused to include notice that these are made under an emergency use authorization period, and refused to disclose the risks and benefits of the product, and also advise me of my right to either accept or refuse the product,[3] and **b)** which of these accommodation measures has the proven efficacy to prevent transmission or infection of the contagious disease for which you regard me as having?

7. How are your requests for my medical information and submitting to medical examinations and interventions necessary for the performance of my employment duties?

8. Why are you able to diagnose me with a deadly disease and impose restrictions and medical interventions without my informed consent, without any physician's oversight or judicial approval, yet I am required to obtain written permission from my physician to exercise my rights to informed consent and medical privacy? We can stipulate that I have never waived any of my rights to medical privacy which includes the right of informed consent as a condition for employment.

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2 29 CFR 1630.2 *et seq.* And 45 CFR Part 84.2 *et seq.*

3 21 USC 360bbb-3

9. Please disclose records of the court's budget approval for using public funds for administering or prescribing health control measures without judicial oversight and approval, without any licensing, insurance or medical training and without the supervision of any physician.

Be advised that it is illegal to condition my employment upon submitting to accommodation measures, this constitutes discrimination based upon disability, a violation of 29 CFR Part 1630, for which I would have a claim for employment discrimination based upon disability.

Sincerely,

Chris Mone

attached:
Memo dated September 1, 2021 "Mandatory Testing Program"
Memo dated September 10, 2021 "Mandatory Vaccination Requirement"
Letter dated September 20, 2021 "Employment Discrimination and Retaliation Based on Disability"

A-11

From: cgrima11@nycourts.gov,
To: c.mone@aol.com,
Cc: MIGBM@nycourts.gov,
Subject: RE: EEOC- Charge-Chris Mone.pdf
Date: Tue, Sep 21, 2021 11:36 am

Mr. Mone,

I should not be included on any further correspondence/communications regarding this matter.

Regards,

Carolyn Grimaldi, Esq.

Director of Human Resources

Office of Court Administration

25 Beaver Street, 7th Floor

New York, NY 10004

Tel: (212) 428-2515

From: c.mone <c.mone@aol.com>
Sent: Monday, September 20, 2021 10:12 PM
To: Carolyn Grimaldi <cgrima11@nycourts.gov>; MIGBM <MIGBM@nycourts.gov>
Subject: EEOC- Charge-Chris Mone.pdf

Ms Grimaldi,

Ms Moy,

Please see attached my EEOC filed complaint.

Thank you

Chris Mone

A-12

Family Court of the State of New York
City of New York

100 RICHMOND TERRACE
STATEN ISLAND, N.Y. 10301

Date: 9-28-2021

From: Captain J. Bonanno

Subject: Unfit for Service

To Employee: C.O. C. Mone

This will confirm you were notified today that you are unfit for service because of your failure to comply with the Unified Court System's Vaccination Mandate that requires every judge and non-judicial employee to submit proof of at least one dose of COVID-19 vaccination to the Revised Mask Policy (Orange Card) share point site or, in the alternative, request for a religious or medical exemption to this mandate by 5:00 PM, September 27, 2021.

This will also confirm that you were advised that you must leave the workplace and/or not report to work until you have submitted the required proof of vaccination or a request for exemption and that has been confirmed by your supervisor.

As indicated in the mandatory Vaccination Policy, employees who fail to comply with the provisions of the Policy are prohibited from reporting to work and may be considered absent without authorization.

Signature of Supervisor John Bonanno

A-13

INVOCATION OF RIGHTS UNDER THE AMERICANS WITH DISABILITIES ACT (as Amended)

CONFIDENTIAL UNDER 29 C.F.R. §1630.14(c)(1)

As an employee of OFFICE OF COURT ADMINISTRATION ("Employer") I am disclosing that I am regarded as disabled under the Americans with Disabilities Act. I hereby invoke the protection of the Americans with Disabilities Act of 1990, and the ADA Amendments Act of 2008, and any corresponding protections under the Rehabilitation Act of 1973. **In an attempt to avoid being deemed "non-compliant" or "unfit for service", I assert the following:**

1. I have a disability that substantially limits more than one major life activity.
2. My disability is the COVID-19 vaccination ("vaccine") mandate {"mandate") and my Employer's implementation of that mandate, and how it specifically affects me.
3. My Employer's vaccine mandate requires me to take a COVID-19 vaccine and this requirement is accompanied by a coercive and intimidating threat that I will be terminated if I do not take the vaccine, and there is only one FDA approved COVID-19 vaccine - COMIRNATY™.
4. My Employer's vaccine mandate implementation uses [check all that apply]:
   - [✓] intimidation;
   - [✓] harassment; [repeated events of coercion, threats, or intimidation]
   - [✓] coercion;
   - [✓] threats, and/or
   - [✓] interference with my rights under the ADA. (of fully informed consent concerning medicine requirements as a mitigation)
5. I have expressed opposition, and/or now express opposition to the mandate, which I consider to be unlawful because it forces me to take a vaccine that **my Employer has not fully and completely disclosed and certified the following information in entirety:**
   - [✓] where, **specifically**, I can obtain the FDA approved COMIRNATY™ vaccine; and/or
   - [✓] a complete list of my certain and absolute risks in taking the vaccine; and/or
   - [✓] any certain and absolute benefits that the vaccine is guaranteed to provide me; and/or
   - [✓] whether or not my Employer has classified my immune system as naturally deficient in providing defense against COVID-19 (any variant); and/or
   - [✓] If my Employer has classified my immune system as naturally deficient in providing defense against COVID-19, I have not received any certified information on how my employer decided that my immune system was naturally deficient in this way; and/or
   - [✓] whether or not my Employer has an insurable risk in providing me health insurance coverage, and if so, whether that insurable risk covers any injuries or harms I may receive from the vaccine; and/or
   - [✓] If I have had COVID-19, my Employer has not provided me with any information that details how the vaccine will affect, either negatively or positively, my naturally developed immune response; and/or
   - [✓] If I am injured by the vaccine, whether or not my Employer assumes any liability or provides any insurance coverage for any injuries I may sustain by the vaccine.
6. I demand that my Employer cease and desist in the actions prohibited under 42 U.S.C. §12203 (a) & (b) and 29 C.F.R. §1630.12 (a) & (b), including coercion, intimidation, threats, harassment, or interference with my ADA rights.
7. I demand that my Employer give me full disclosure on the foregoing items listed above, so that I may regain my ability to enjoy my ADA rights free from coercion, intimidation, threats, harassment or interference.
8. **I demand that my employer inform me, along with the other withheld information that allows my full and informed consent, to immediately reveal to me the specific place that is local to me where the FDA Approved COMIRNATY™ vaccine is available, and the full and complete list of ingredients of the COMIRNATY™ vaccine.**
9. This is a protected activity under 29 C.F.R. 1630.12(a) & (b).

Please provide me equal access to my ADA rights as stated hereon, and respond timely in writing. I will trust that my efforts to remain in good faith are reciprocated.

EMPLOYEE NAME CHRISTOPHER MONE EMPLOYEE SIGNATURE _____ Date: 9/29/21

A-14

U.S. EQUAL EMPLOYMENT OPPORTUNITY COMMISSION
New York District Office

33 Whitehall Street, 5th Floor
New York, NY 10004-2112
Intake Information Group: (800) 669-4000
Intake Information Group TTY: (800) 669-6820
New York Direct Dial: (929) 506-5270
FAX (212) 336-3625
Website: www.eeoc.gov

BY ELECTRONIC MAIL

Chris Mone
83 Windsor Road
Staten Island, NY 10314
Email: c.mone@aol.com

Mone v. New York State Unified Court System
EEOC # 520-2021-04972

Dear Mr. Mone,

This is with reference to your correspondence and subsequent communication with this office in which you alleged discrimination in violation of the American with Disabilities Act of 1990, as amended, by the above-named Respondent.

As discussed in our conversation on **Oct. 8, 2021,** a review of all available information provided failed to indicate that a violation of the statute(s) has occurred; however, this does not certify that Respondent is in compliance with the statutes. While we fully understand that the parties to a charge often have very firm views that the evidence supports their respective positions, our final determinations must comport with our interpretations of the available evidence and the laws we enforce. For this reason, we will issue you a Dismissal and Notice of Rights, which will enable you to file suit in U.S. District Court within 90 days of your receipt of that Notice if you wish to pursue this matter further.

We regret that we could not be of further service to you in this matter.

Sincerely,

Robert Rullan Digitally signed by Robert Rullan Date: 2021.10.08 10:54:06 -04'00'

Date

Investigator

cc. Attorney for Charging Party.

A-15

From: c.mone@aol.com,
To: hernan.morales@eeoc.gov, david.reinman@eeoc.gov, complaints@dhr.ny.gov,
Subject: I am sharing '2021+Oct+8+Mone+letter+520+2021+04972' with you
Date: Tue, Oct 19, 2021 8:40 pm
Attachments: 2021+Oct+8+Mone+letter+520+2021+04972.pdf (185K)

This was on my EEOC portal.
I never had a conversation with this gentleman on October 8, 2021. This is outright not true.
Someone needs to contact me. He does not put his contact information on this document. This is very disappointing to fabricate a conversation
Please contact me at 917-699-3654
Thank you
Chris Mone

Sent from my Verizon, Samsung Galaxy smartphone

U.S. Department of Justice

Civil Rights Division

Disability Rights Section – 4 Con
950 Pennsylvania Ave, NW
Washington, DC 20530

A - 16

December 7, 2021

VIA EMAIL:c.mone@aol.com

Chris Mone
83 Windsor Road
Staten Island, NY 10314

Re: EEOC Charge Against: New York State Unified Court System
EEOC No.: 520-2021-04972

Dear Mr. Mone:

NOTICE OF RIGHT TO SUE WITHIN 90 DAYS

Because you filed the above charge with the Equal Employment Opportunity Commission, and the Commission has determined that it will not be able to investigate and conciliate that charge within 180 days of the date the Commission assumed jurisdiction over the charge, and the Department has determined that it will not file any lawsuit(s) based thereon within that time, and because you or your attorney has specifically requested this Notice, you are hereby notified that you have the right to institute a civil action against the above-named respondent under Title I of the Americans with Disabilities Act of 1990, 42 U.S.C. 12111, et seq. If you choose to commence a civil action, such suit must be filed in the appropriate court within 90 days of your receipt of this Notice. This should not be taken to mean that the Department has made a judgment as to whether or not your charge is meritorious.

If you or your attorney has any questions concerning this matter or wish to inspect the investigative file, please address your inquiry to: New York District Office, U.S. Equal Employment Opportunity Commission. Please note, due to COVID-19 there may be a delay in obtaining copies of the case file.

Enclosed you will find a Notice of Rights under the ADA Amendments Act of 2008 (ADAAA). We are forwarding a copy of this Notice of Right to Sue to the Respondent in this case.

Sincerely,
Kristen Clarke
Deputy Assistant Attorney General
Civil Rights Division

BY: /s/ Celeste A. Adams-Simmons
Celeste A. Adams-Simmons
Senior Investigator
Disability Rights Section

Enclosures:
Notice of Rights under the ADAAA

cc: New York State Unified Court System
EEOC- New York District Office

A-17

Chris Mone
email: c.mone@aol.com

Eva Moy, OIGBM Office of Court Administration 25 Beaver Street New York, New York 10004 email: migbm@nycourts.gov	Robert Rullan, Investigator New York District Office EEOC 33 Whitehall Street, 5th Floor New York, NY 10004 email: robert.rullan@eeoc.gov
Captain Bonano 100 Richmond Terrace Staten Island NY 10301 email: rbonnano@nycourts.gov	Kelvin Smart Office of Court Administration 25 Beaver Street New York, New York 10004 KSMARTT@nycourts.gov

November 1, 2021

Re: Notice of Timely Response to Retaliation of Being Declared Unfit to Serve and/or Uncompliant Based on Disability

In an effort to not be declared "unfit to serve" or "non-compliant" by my employer I state the following: I have, in fact, responded to every injection status survey request by noticing my employer that I am claiming the "exemption" of not waiving my rights under the ADA. I am fit for work, ready for work and am not declining work. The survey you ask me to respond to is discriminatory because it classifies me as either "vaccinated" or "unvaccinated" and will treat me differently based upon my classification.

I have been responsive to every request. The survey does not have an option to opt-out of the survey based upon rights protected by the ADA which may be considered as **interference** with my rights under the ADA; therefore I will not jeopardize my rights by using the form. Instead, this notice constitutes my timely response to your request for "compliance" information and as my declaration of "exemption" under the protections of the ADA "regarded as" prong.

I was given the attached Unfit to Serve notice which states that NYSUCS retaliated against me and terminated me for the disability of being unvaccinated and because it regards me as disabled as a potential or actual source of COVID-19 without any individualized assessment. It further incorrectly states that I have not registered my "exemption". I claimed exemption to the "vaccine mandate" policy because I invoked my rights under the ADA using the "regarded as prong" and because I am claiming interference with my rights since my employer is refusing to recognize this claim as a valid "exemption" from the policy.

At what point did my employer conspicuously disclose that complying with a COVID-19 vaccine requirement, testing requirement, or masking requirement is an essential function of my job?

My employer regards me as having a disability

NYSUCS regards me as disabled by classifying me as a *potential or actual source* of COVID-19. The affirming action of regarding me as a potential or actual source is that I have been given the coercive, threatening, and intimidating choice to vaccinate or be terminated.

Employer regards me as disabled through its classification of me as *unvaccinated*, and the affirming action of regarding me as *unvaccinated* is that I was terminated on September 29, 2021 on the basis of being *unvaccinated*. These factors are based solely upon my employers perception of my physical condition.

My employer's policy creates a disability for me because it is an impairment that substantially limits my ability to do my job because my employer refuses to let me do my job without first submitting to its offered accommodations. My employer has failed or refused to conduct any individualized assessment to determine whether or not I am a direct threat.

My employer can label this however it wishes to attempt to avoid this truth, but the classification of my vaccination status as "unvaccinated" has caused me to be fired. NYSUCS has used policies and procedures that are intimidating, threatening, coercive, and that interfere with ADA rights, and this is prohibited under the ADA.

All employer's forms requesting injection status because my employer is treating me as impaired (contagious) and regarding me as disabled and are discriminatory because they classify me on the basis of my employer's perception of my physical condition.

"Regarded as" means that the person either:

- Has an impairment that does not substantially limit a major life activity;
- Has an impairment that substantially limits a major life activity only as a result of the attitudes of others toward them; or
- Does not have any impairment, but is treated by an entity as having an impairment. [1]

My employer is Interfering with my rights under the ADA

NYSUCS has deceptively tried to persuade me that my only remedy to the illegal policy demands would be to ask for a medical or religious exemption from these discriminatory policies and practices, thereby creating a false record that is without legal merit. NYSUCS only presented a medical or religious exemption, and did not even mention that ADA accommodations are available; which is obfuscation of and interference with my exercise and enjoyment of the rights held under the ADA, particularly 42 USC 12203(b) and 29 CFR 1630.12(b).

From the EEOC website, number 19, "Interference":

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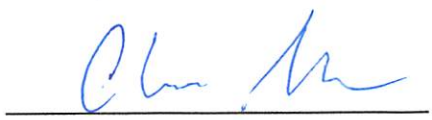
1 https://adata.org/faq/what-does-regarded-having-disability-mean

"Examples of interference include: issuing a policy or requirement that purports to limit an employee's rights to invoke ADA protections (e.g., a fixed leave policy that states 'no exceptions will be made for any reason');"[2]

All employer's forms which only offer medical or religious exemption as the only "opt-out" ("exemption") choices interfere with my ADA rights because they limit an employee's right to invoke ADA protections of the 'Regarded As" prong, including without limitation, the right to be free of discrimination and retaliation based upon disability, such as being terminated or segregated because of one's physical condition.

I am claiming exemption to the policy based upon my ADA rights under the "Regarded as" prong which entitles me to the protections of the ADA. My exemption status also precludes me using any accommodation measures/mitigation measures, as I am not required to accept them.



Chris Mone

2https://www.eeoc.gov/laws/guidance/questions-and-answers-enforcement-guidance-retaliation-and-related-issues

B

Classification of Products as Drugs and Devices & Additional Product Classification Issues: Guidance for Industry and FDA Staff

FINAL GUIDANCE

Additional copies are available from:
Office of Combination Products
Food and Drug Administration
WO32, Hub/Mail Room #5129
10903 New Hampshire Avenue
Silver Spring, MD 20993
(Tel) 301-796-8930
(Fax) 301-847-8619
http://www.fda.gov/CombinationProducts/default.htm.

For questions regarding this document contact the Office of Combination Products at 301-796-8930 or combination@fda.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Office of Combination Products
Office of Special Medical Programs
Office of the Commissioner

September 2017

Table of Contents

Contains Nonbinding Recommendations

Classification of Products as Drugs and Devices & Additional Product Classification Issues: Guidance for Industry and FDA Staff[1]

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page of this guidance.

I. INTRODUCTION[1]

FDA regularly receives questions from medical product sponsors concerning the classification of their products.[2] We believe that efficient, effective regulation is facilitated by providing guidance on issues frequently raised in relation to Requests for Designation (RFDs) and other classification activities. In addition, providing as much clarity and predictability as possible with respect to product classifications should enable informed planning for product development. Accordingly, we have prepared this guidance to make the Agency's current thinking concerning certain product classification issues more readily and widely available.

While issues have arisen relating to whether a product should be classified as a drug, device, biological product, or combination product, most of these issues have related to whether a product should be classified as either a drug or a device.[3] Accordingly, this guidance focuses particularly on cases in which a product[4] may be classified as a drug or device.[5] This guidance also addresses additional issues relating to product classification, including how to obtain classification determinations from FDA for medical products.

This guidance is organized into two substantive sections.

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[1] This guidance has been prepared by the Office of Combination Products in consultation with the Center for Biologics Evaluation and Research, the Center for Devices and Radiological Health, and the Center for Drug Evaluation and Research.

[2] Please note that "classification" as used in this guidance refers to a product's designation as a drug, device, biological product, or combination product. This is distinct from the use of the term "classification" in reference to the class (Class I, II, or III) of a device as described in section 513(a) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

[3] This guidance addresses the definitions for the terms drug, device, and biological product in section III. The term "combination product" is defined in 21 CFR 3.2(e). For further information regarding the definition for the term combination product and the regulation of combination products, please visit the webpage for the Office of Combination Products at www.fda.gov/CombinationProducts/default.htm.

[4] The guidance's discussion of the classification of products is also relevant to classification of the constituent parts of a combination product.

[5] This guidance focuses on classification of products for human use. Distinct considerations may apply in determining how to classify a product intended for use in animals.

Section II offers guidance on the RFD process for obtaining a formal determination of a product's classification.

Section III presents general concepts regarding FDA's decision-making process for classification determinations and addresses issues that may arise in determining whether products should be classified as drugs or devices.[6]

The Agency recommends that sponsors contact the Office of Combination Products (OCP) to confirm the classification of any products they may wish to market if the appropriate classification is unclear or in dispute. Section IV provides contact information for OCP and responses to frequently asked questions.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word "should" in Agency guidances means that something is suggested or recommended, but not required.

II. WHAT IS THE PROCESS FOR OBTAINING A FORMAL CLASSIFICATION DETERMINATION FOR A PRODUCT?

If the classification of a product as a drug, device, biological product, or combination product is unclear or in dispute, a sponsor can submit an RFD to OCP in accordance with Part 3 of Title 21 of the Code of Federal Regulations (21 CFR Part 3) to obtain a formal classification determination for the product, as provided for under section 563 of the FD&C Act (21 USC 360bbb-2). Any RFD determined to be incomplete will be returned to the sponsor with a request for the missing information.[7] 21 CFR 3.8(a). Once OCP determines the RFD is complete for filing, the Agency reviews the RFD.

The sponsor recommends a classification in the RFD, and should explain the basis for the recommendation. While the sponsor should justify why it believes the product meets the recommended classification, we generally consider both the information provided in the RFD and other information available to the Agency at that time in making our designation.

Generally, OCP will respond to the sponsor in writing within sixty days of the RFD filing, identifying the classification of the product as a drug, device, biological product, or

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[6] This section generally focuses on approaches for determining whether a product should be classified as a drug or a device, based on application of the statutory definitions for these terms under sections 201(g) and 201(h) of the FD&C Act (21 USC 321(g) and (h)), respectively. Please note that this document does not focus on the classification of products as biological products regulated under section 351(i) of the Public Health Service Act (PHS Act) (42 USC 262(i)). It also does not address under what circumstances certain human cells, tissues, or cellular or tissue-based products (HCT/Ps), as defined in 21 CFR Part 1271, are regulated solely under section 361 of the PHS Act. For guidance concerning HCT/Ps, please visit http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Tissue/.

[7] See 21 CFR 3.7 for content requirements for RFDs.

combination product. If the Agency does not provide a written response within sixty days, the sponsor's recommendation respecting the classification of the product is considered to be the final determination. 21 USC 360bbb-2(b) and (c).

RFD determinations pertain only to the product as described in the designation letter, including its proposed use(s) or indication(s) for use. The Agency may modify a determination made under section 563 regarding the classification of a product or the component of FDA that will regulate the product either with the written consent of the sponsor or for public health reasons based on scientific evidence. 21 USC 360bbb-2(b) and (c).[8]

A new determination may be appropriate if there is a change in, for example, a proposed indication for use or in a component of the product, or if the sponsor or Agency becomes aware of additional information that reveals that the means by which the product achieves its primary intended purposes differ from what was originally described in the RFD. For example, if a sponsor wished to change the indication for a product and that new indication would be achieved through a different mechanism than the original indication, a different classification for the new indication might be appropriate.

Please contact OCP if you have questions regarding whether to submit an RFD, what information to provide, or issues to address in an RFD to ensure its completeness and clarity.[9]

III. WHAT DOES FDA CONSIDER IN DETERMINING WHETHER TO CLASSIFY A PRODUCT AS A DRUG OR DEVICE?

FDA's determination of whether to classify a product as a drug or device is based on statutory definitions, as set forth in sections 201(g) and 201(h) of the FD&C Act, respectively. We apply these definitions to products, relying on the scientific data that are available to FDA at the time of the classification determination concerning the product for its proposed use(s)/indication(s).[10]

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[8] The sponsor may request reconsideration of the decision if its classification recommendation is not adopted by the Agency. See 21 CFR 3.8, 10.75. If the sponsor develops or becomes aware of new information that may affect the product's classification, the sponsor may also submit a new RFD seeking a new determination.

[9] More detailed information on the RFD process is provided in OCP's guidance *How to Write a Request for Designation (RFD), available at* http://www.fda.gov/RegulatoryInformation/Guidances/ucm126053.htm. A pre-RFD process is available if a sponsor wishes to obtain a preliminary, non-binding classification determination or to engage in preliminary classification discussions with the Agency before filing a formal RFD. The RFD and pre-RFD processes are also available to sponsors to clarify the Center assignment for medical products, though this issue is beyond the scope of this guidance. More information about the pre-RFD process is available at https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM534898.pdf.

[10] If a product type has been classified by regulation, FDA would generally classify the product (including as a constituent part of a combination product) in accordance with the regulation, if the product (or constituent part) falls within the scope of that regulation. If the Agency concludes that it may be appropriate to propose changing a classification established by regulation, FDA would initiate notice and comment rulemaking to do so.[11] The device definition also includes a second exclusionary clause stating that a device "is not dependent upon being metabolized for the achievement of its primary intended purposes." This clause has not been at issue frequently in classification determinations. Accordingly, we do not offer guidance on its construction here. If sponsors have questions regarding the Agency's interpretation of this clause, they may contact OCP.

Medical product classification determinations often focus substantially on whether a product that meets the definition of drug also meets the statutory definition of device. This section presents the drug and device definitions and discusses how the Agency addresses certain issues that arise when determining whether a product should be classified as a drug or device.

A. Statutory Definitions

1. Drug

Section 201(g) of the FD&C Act (21 USC 321(g)) provides that the term "drug" means:

> (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C). . . .

2. Device

Section 201(h) of the FD&C Act (21 USC 321(h)) provides that the term "device" means:

> an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is--
> (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them,
> (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
> (3) intended to affect the structure or any function of the body of man or other animals, and
>
> which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.

B. Certain key provisions of the definition of device

Conceptually, all FDA-regulated medical products meet the definition of "drug" under section 201(g) of the FD&C Act, due to the broader scope of the drug definition. For a medical product also to meet the more restrictive device definition under section 201(h) of the FD&C Act, it must (i) be "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article," and (ii) "*not* achieve its primary intended purposes through *chemical action* within or on the body of man or other animals" and (iii) "*not* [be] dependent upon being *metabolized* for the achievement of its primary intended purposes" (emphasis added).

The sponsor presumably has the most complete information relevant to how its proposed product achieves its primary intended purpose(s). Sponsors seeking a classification determination should present all available data and other information potentially relevant to that determination (without regard to whether the data or information supports the sponsor's preferred outcome). For example, for a sponsor seeking to classify its proposed product as a device, those data should demonstrate that its product meets the definition of a device.

At the classification stage, sponsors would not be expected to have gathered sufficient data to demonstrate that their proposed product meets the applicable marketing authorization standard (e.g., data demonstrating effectiveness). Therefore, the focus of FDA's classification analysis is on how the product would be expected to achieve its primary intended purposes, assuming it is capable of achieving its primary intended purposes at all. FDA will use its best scientific judgment to evaluate all available information relevant to the classification determination, including information submitted by the sponsor or available in the literature.

The following discussion presents the Agency's current thinking on certain issues that arise with respect to the statutory definition of device.

1. "Similar or related article" in the definition of device

The first clause of the device definition provides that the term "means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or *other similar or related article* . . ." (emphasis added). The issue of whether a product may be considered a "similar or related article" under this clause can arise, for example, with regard to products in liquid, semi-liquid, gel, gas, or powder form. In some cases, such products are appropriately considered "similar or related articles," and may be classified as devices, so long as they also satisfy the remainder of the device definition under section 201(h) of the FD&C Act, including the chemical action exclusion discussed in section III.B.3 below. This could be the case, for example, for gels or powders put on the skin as a barrier, gases used as space fillers, or liquids used to clean either surgical instruments or contact lenses.

2. "Primary intended purposes" in the definition of device

Most often, in determining whether a product meets the device definition, questions arise concerning the exclusionary clause of the definition, which provides that a device is a product "which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals . . . ."[11] A product that has chemical action could be a device if it does not achieve its primary intended purposes through that chemical action.

[11] The device definition also includes a second exclusionary clause stating that a device "is not dependent upon being metabolized for the achievement of its primary intended purposes." This clause has not been at issue frequently in classification determinations. Accordingly, we do not offer guidance on its construction here. If sponsors have questions regarding the Agency's interpretation of this clause, they may contact OCP.

For example, if the primary intended purpose of a hip joint replacement implant is to restore movement, and the implant also elicits a foreign body response through chemical action, that response would not be considered a primary intended purpose of the implant. Accordingly, such an implant could be classified as a device despite the chemical action, because such action does not achieve the product's primary intended purpose. Similarly, if the primary intended purpose of an absorbable suture is to rejoin tissue, and the suture is also designed to be resorbed by the body through a combination of chemical action and metabolic activities, such resorption would not be considered a primary intended purpose of the product. Accordingly, such an absorbable suture could be classified as a device despite the chemical action and metabolic activity, because such action or activity does not achieve the product's primary intended purpose.

3. "Chemical action" in the definition of device

FDA frequently receives questions from product sponsors concerning the Agency's interpretation of the term "chemical action." This term must be read in the context of the statutory definition of "device" as a whole. The determination of whether a product meets the device definition does not depend solely on whether the product exhibits "chemical action." In particular, as explained in section III.B.2 and 4, a product that exhibits chemical action will still meet the device definition if the product "does not achieve its primary intended purposes through" that chemical action "within or on the body," and otherwise satisfies the device definition.

Under the Agency's interpretation of the device definition, a product exhibits "chemical action" if it interacts at the molecular level with bodily components (e.g., cells or tissues) to mediate (including promoting or inhibiting) a bodily response, or with foreign entities (e.g., organisms or chemicals) so as to alter that entity's interaction with the body.[12] We note that this type of interaction is consistent with the term "pharmacological action" as that term is generally understood in the medical field. Accordingly, we have used "pharmacological action" as a short-hand throughout the rest of this guidance for ease of explication and recognition. The examples presented in section III.B.5 offer illustration of FDA's interpretation of chemical action.

4. "Within or on the body" in the definition of device

Because a device "does not achieve its primary intended purposes through chemical action *within or on the body* of man or other animals" (emphasis added), a product can be a device even if it achieves its primary intended purposes through chemical action, so long as the chemical action does not occur "within or on the body" (and the product meets the other elements of the definition of device under section 201(h)).

Whether chemical action is occurring "within or on the body" is generally a straightforward matter. If the chemical action is occurring inside the body or on the surface of the body, it is within or on the body. For example, the chemical action of an orally ingested pill

[12] For purposes of this interpretation, an interaction at the molecular level occurs through either chemical reaction (i.e., formation or breaking of covalent or ionic bonds), intermolecular forces (e.g., electrostatic interactions), or both. The mere exchange of non-chemical energy (e.g., electromagnetic or thermal energy) between a product and the body would not constitute "chemical action."

or tablet of a decongestant would be "within the body," and the chemical action of a spray or cream for treatment of dermatitis when applied to the skin would be "on the body." Similarly, it is generally a straightforward matter to determine that chemical action is not occurring within or on the body. For example, the chemical action of an antimicrobial agent used to clean a surgical instrument before that instrument is used is not occurring within or on the body.

However, the Agency has on occasion considered some situations in which it may be less clear whether chemical action is occurring within or on the body. For example, we have determined that chemical action occurring solely within an extracorporeal device, specifically a kidney hemodialysis machine, is not occurring within or on the body. Similarly, we have determined that the chemical action of a transport solution to preserve a donor organ for transplantation while in an organ transport container is not occurring within or on the body.

5. Illustrative Examples

The following examples further illustrate the application of some of the key provisions of the device definition discussed above. Table 1 contains some examples of medical products that achieve their primary intended purposes through chemical action within or on the body. Table 2 contains some examples of medical products that do not achieve their primary intended purposes through chemical action within or on the body.

Table 1: Examples of Medical Products that Achieve Their Primary Intended Purposes through Chemical Action within or on the Body

Product	Description
Aspirin	Aspirin is used for pain relief. Acetylsalicyclic acid (aspirin) contains an acetyl group that has the ability to covalently bind to a serine residue of a cyclooxygenase enzyme (COX-1 or COX-2). This is considered pharmacological action because it inactivates the enzyme and thereby inhibits the synthesis of prostaglandin and thromboxanes, which suppresses the body's inflammatory response for pain relief.
Beta Blockers	Beta blockers are used to reduce blood pressure. Cells contain beta receptors that can be stimulated by neurotransmitters such as adrenaline/epinephrine. Beta blockers, like propranolol, bind beta receptors (b1 and b2) and exhibit pharmacological action by inhibiting the activation of the signaling cascade. This blockage causes cardiac cells to reduce the strength of cardiac contractions and heart rate.
Magnesium Sulfate	Magnesium sulfate is used as replacement therapy for magnesium deficiency. It acts as a catalyst in enzymatic reactions (a molecular-level interaction). While the chemical or atomic structure of magnesium sulfate is not altered, its participation in enzymatic reactions is considered a pharmacological action because it impacts various cellular and molecular processes.

Polymyxin B Sulfate	Polymyxin B sulfate is an antibiotic that is used to treat bacterial infection. It is composed of a cationic protein surfactant that has fatty acid functional groups. Polymyxin B sulfate acts through intermolecular forces, by binding to components of the bacterial membrane (i.e., the membrane of the foreign entity) and by association/fusion of the fatty acid portion of the molecule with the lipid bilayer via hydrophobic interactions. This binding is a pharmacological action because it disrupts the integrity of the bacterial membrane, which causes organism death, thereby treating the bacterial infection.
Hydroxocobalamin	Hydroxocobalamin is used as an antidote to cyanide poisoning. The cobalt moiety of hydroxocobalamin exhibits pharmacological action because it chemically reacts with cyanide, a toxic chemical agent, to form cyanocobalamin, a non-toxic compound, and the ability of hydroxocobalamin to interact with cyanide facilitates the removal of the toxic agent in order to inhibit the toxic effects of cyanide on the body.

Table 2: Examples of Medical Products That Do Not Achieve Their Primary Intended Purposes through Chemical Action within or on the Body

Product	Description
Abdominal Adhesion Barrier	Inert, biodegradable synthetic polymers can be used to reduce post-operative adhesions with tissues and organs within the abdominal cavity. An implanted physical barrier sheet composed of such polymers would act to reduce adhesion through physical separation of tissue and not through pharmacological action on the surrounding tissue.
Polymethylmethacrylate (PMMA)	PMMA is an acrylate polymer that is used as a temporary bone spacer. PMMA is built from methyl methacrylate monomer units, which undergo free radical polymerization in the presence of an initiator compound. The molecules that are part of the polymerization process interact with each other to create a solid mass to fill a bone void physically. The process does not require an interaction between the PMMA and the bone at the molecular level and, therefore is not considered chemical action within or on the body.
Topical Surgical Adhesive	Cyanoacrylate is an acrylic resin that is used to approximate skin tissue as an adjunct to a wound closure product. The resin undergoes anionic polymerization in the presence of water. The chemical reaction that occurs between the resin and ions in the water allows it to form into long polymer chains. This type of adhesive can bond to a cut/incision, creating a physically-intact film to aid in keeping skin edges together. While the product binds to tissue, it does not exhibit pharmacological action because that binding does not mediate a bodily response.

Gold Nanoparticles	Nanoparticles composed of gold can be used to treat cancer. When gold nanoparticles are injected into a tumor site and exposed to electromagnetic energy, they absorb the electromagnetic energy and convert it to thermal energy, and this heat is transferred to the surrounding cells or tissue. The heat transfer, as opposed to a binding interaction with the nanoparticle, causes the cancer cells to die. Therefore, this effect is not achieved through chemical action.
Cryosurgery for Wart Removal	Cryogen (liquid gas), such as nitrogen or dimethyl ether, is used to treat common and plantar warts. The liquid gas is extremely cold and freezes the wart, resulting in damage to the topmost layer of cells. A physiological effect (i.e., cell death) results from heat transfer, not from a binding interaction with the gas. Therefore, the freezing is not considered chemical action.
Dental Amalgam	A resin that fills a cavity in a tooth as part of the treatment of dental caries may bind to the tooth via covalent bonding, or rely in part on intermolecular forces to change from liquid or paste to solid form. However, this binding and/or state change does not mediate a bodily response, but rather produces a solid mass, to fill the cavity. Therefore, it would not be considered chemical action.
Respirator Mask with Antimicrobial Filter	An antimicrobial product impregnated into a filter on a respirator mask to kill microbes that the user might otherwise inhale would exhibit pharmacological action. However, while the mask is in contact with the user's face, the filter is not. So, the chemical action occurring on the filter is not occurring within or on the body.

C. How is a product classified if it meets the definition for drug (or for both drug and device) and also meets the definition for biological product?

As explained in section III.B, products that meet the device definition in 201(h) of the FD&C Act also meet the drug definition in 201(g) of the FD&C Act. In addition, products that meet the drug definition, or both the drug and device definitions, may also meet the definition of biological product under section 351(i) of the PHS Act (42 USC 262(i)).

Section 351(i) provides that:

> The term "biological product" means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide),[13] or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.

[13] For guidance on FDA's interpretation of the category "protein (except any chemically synthesized polypeptide)" see *Biosimilars: Questions and Answers Regarding Implementation of the Biologics Price Competition and Innovation Act of 2009*, at Q.II.1 (April 2015), *available at* http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM444661.pdf.

Products that meet the drug definition and that also meet the definition of biological product are classified as biological products, and are generally subject to licensure under the PHS Act.[14] Products that meet the definitions for drug, device, and biological product may also be classified as biological products. If you have questions regarding whether a product meets the definition of biological product or how this might affect its classification, please contact OCP.

IV. ADDITIONAL INFORMATION

For further information on the classification of products as devices, drugs, biological products, or combination products, please refer to the Frequently Asked Questions on the next page, OCP's webpage at https://www.fda.gov/CombinationProducts/default.htm or contact OCP at:

Office of Combination Product
Food and Drug Administration
WO32, Hub/Mail Room #5129
10903 New Hampshire Avenue
Silver Spring, MD 20993

(Tel) 301-796-8930
(Fax) 301301-847-8619
combination@fda.gov

[14] Certain biological products have been historically approved under the FD&C Act and may continue to be subject to approval under the FD&C Act until March 23, 2020. See Section 7002(e) of the Biological Price Competition and Innovation Act of 2009; see also FDA, *Implementation of the "Deemed to be a License" Provision of the Biologics Price Competition and Innovation Act of 2009, available at* https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-drugs-gen/documents/document/ucm490264.pdf.

FREQUENTLY ASKED QUESTIONS

1. Can a product be classified as a device if it exhibits "chemical action"?

   Yes, if the product does not achieve its primary intended purposes through chemical action within or on the body and otherwise meets the definition of a device. However, products that meet the device definition may be regulated as drugs or biological products in some cases. See question 2.

2. If a product meets the definition for drug at 21 USC 321(g) and for device at 21 USC 321(h), how is it classified?

   Generally, the product would be classified as a device, unless it falls within a special category (for example, apparatuses used in the preparation of compounded positron emission tomography drugs are classified as drugs, see 21 USC 321(ii)).

3. Can the proposed use or indication of a product affect its classification?

   Yes. Two products with exactly the same composition can be classified differently based on their primary intended purposes. For example, if a vaginal product is intended solely to facilitate ease and comfort during sexual intercourse and it achieves this through lubrication that decreases friction (via mechanical/physical action) and not through chemical action, it is classified as a device. However, the same product can be classified as a drug if it is intended, for instance, to alter pH, control odor, or prevent infection, and does so through chemical action as discussed in III.B.3 above.

4. What should you do if, after reviewing this guidance, you are unsure of how your product is classified?

   You should contact the Office of Combination Products (Combination@FDA.GOV) for feedback. OCP will provide you feedback, including on whether a pre-RFD or an RFD may be appropriate and what information you should provide.

5. Where can you find additional information about product classification?

   Additional information on classification is posted on OCP's webpage at:(https://www.fda.gov/CombinationProducts/AboutCombinationProducts/ucm101496.htm)

   For additional information on how to submit an RFD, see *How to Write a Request for Designation (RFD)* (http://www.fda.gov/RegulatoryInformation/Guidances/ucm126053.htm).

   More information about the pre-RFD process is available at https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM534898.pdf .

C

TITLE: NEW YORK STATE COURT OFFICER

Effective Date: 01/08/2004
Title Code Number: 946700
Salary Grade: 18
Jurisdictional Classification: C

DISTINGUISHING FEATURES OF WORK:

Under the direct supervision of a New York State Court Officer-Sergeant and the general supervision of the court clerk or other security supervisory personnel, New York State Court Officers are responsible for maintaining order and providing security in courtrooms, court buildings, and grounds. NYS Court Officers are assigned to all trial courts and court agencies. NYS Court Officers are peace officers, required to wear uniforms, and may be authorized to carry firearms, execute warrants, make arrests and may coordinate the activities of other court security personnel.

TYPICAL DUTIES:

Provides security by standing in the courtroom and patrolling the courthouse.

Guards criminal defendants accused of both misdemeanors and felonies while in the courtroom and may escort them to and from detention pens.

Assumes a post or patrols the courthouse to maintain order by removing or calming disruptive individuals; bars entry into security areas or courtrooms of people not properly attired or behaved; talks to potentially disruptive prisoners or spectators to calm them.

Physically restrains unruly individuals.

Arrests individuals according to established procedures.

Escorts, guards, and delivers material to sequestered juries.

Escorts judges, juries, witnesses and prisoners to and from the courtroom.

Administers first aid and assistance to individuals during emergencies, accidents or illnesses.

Provides assistance in emergency situations.

Operates security equipment, including magnetometers, handheld screening devices and package x-ray machines.

Uses established search procedures to assure that no weapons or electronic or photographic equipment are brought into the courtroom.

Checks to ensure that all necessary documents are available prior to court sessions.

Checks bench to ensure that Judge has adequate supplies, proper forms, and other materials.

Displays and safeguards exhibits in the courtroom.

Maintains and updates court records.

Distributes and posts appropriate documents and court materials.

Checks any emergency or special equipment such as oxygen tanks, walkie-talkies, and other items to ensure that the equipment is in good working order; reports inoperative equipment to supervisor.

Provides general information to visitors on court premises.

Prepares incident reports.

The above statements are intended to describe the general nature and level of work being performed by persons assigned to this title. They do not include all job duties performed by employees in this title, and every position does not necessarily require these duties.

KNOWLEDGE, SKILLS, AND ABILITIES:

Knowledge of court procedures and practices, court forms, and legal terminology.

Knowledge of laws concerning arrest, use of physical force, and search procedures.

Knowledge of regulations and procedures for handling prisoners.

Knowledge of first-aid.

Knowledge of the rules of evidence and the proper procedures for handling evidence and exhibits.

Knowledge of the laws, rules and regulations concerning weapons and the use of firearms.

Knowledge of regulations and procedures for handling prisoners.

Skill in completing and organizing court documents, forms, and other records.

Skill in administering first aid and using emergency equipment.

Skill in conducting searches and using security equipment.

Skill in using weapons.

Ability to apply knowledge, prior experience, facts, rules, regulations, and directions to specific situations.

Ability to identify and evaluate situations, events and conditions relating to observable activities.

Ability to exercise judgement and common sense.

Ability to carry out established security procedures in case of fire, bomb threat, or other emergency situations.

Ability to observe detail, remember facts and information, and evaluate situations.

Ability to understand oral and written instructions and apply information, rules, regulations, and procedures, to specific situations.

Ability to prepare brief written communications.

Ability to communicate information orally to the public and court or court-related personnel.

Ability to stand and walk for lengthy periods.

Ability to use firearms, self-defense and restraint techniques, and security equipment.

Ability to supervise other workers and to check staff performance.

RELATED TITLES:

Title	*Position in Title Series*	*Distinguishing Characteristics*
New York State Court Officer-Trainee (JG-14)	Entry Level	Serves a two year traineeship.
New York State Court Officer (JG-18)	**Mid-level (Automatic promotion)**	**Provides court security in courtrooms, court buildings and grounds.**
New York State Court Officer-Sergeant (JG-19)	Entry level Supervisor (Promotional)	Supervises security team of subordinate security personnel, provides on the job training and evaluates the performance of subordinates.
New York State Court Officer-Lieutenant (JG-22)	Supervisory (Promotional)	On-site supervisor second in charge to New York State Court Officer-Captain.

QUALIFICATIONS:

At the time of appointment, a New York State Court Officer candidate must have served a two year traineeship as a New York State Court Security Trainee.

Candidates must be legally eligible and qualified to carry firearms.

New York State residency is required for appointment.

Candidates must be citizens of the United States.